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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/758,260	01/16/2004	Ryuji Ueno	247792US0X	5697

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OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
FAY, ZOHREH A	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 03/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/758,260	UENO, RYUJI	
	Examiner	Art Unit	
	Zohreh Fay	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 1-19 are presented for examination.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for certain macrolide compounds for treating dry eye, does not reasonably provide enablement for all macrolide compounds capable of treating dry eye. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are:

1) The nature of the invention:

The claims are drawn to a macrolide compound being used for treating dry eye or conditions associated with dry ere syndrome.

2) The state of the prior art:

According to Lance, Current Medical Diagnosis & Treatment, 43RD Edition, p.152, treatment of dry eye depends on the cause. Aqueous deficiency can be by replacement of the aqueous component of tears with artificial tear. Lacrimal punctual occlusion by canalicular plugs or surgery is useful in sever cases. The state of the art does not

recognize that one group of compounds or one type of treatment is effective for the treatment of dry eye.

3) The relative skill of those in the art:

The relative skill of those in the art is high.

4) The predictability and unpredictability of the art:

The unpredictability of the pharmaceutical and chemical art is high.

5) The breadth of the claims:

The claims are very broad and encompass the use of any macrolide compound for the treatment of dry eye or the conditions associated with dry eye.

6) The amount of direction or guidance presented:

Applicant's specification provides guidance and it is only enabled for the treatment of dry eye using a few macrolide compounds for the treatment of dry eye. However, the specification provides no guidance, to enable one of ordinary skilled in the art to use the invention commensurate in scope with the claims. In re Dreshfield, 110 F.2d 235, 45 USPQ 36 (CCPA 1940), gives this general rule: " It is well settled that in cases involving chemical and chemical compounds, which differ radically in their properties it must appear in an applicant's specification either by enumeration of a sufficient number of the members of a group or by other appropriate language, that the chemicals or chemical combinations included in the claims are capable of accomplishing the desired results". Applicant's specification does not set forth a representative number of examples of macrolide compounds being capable of treating dry eye or the discomfort and damage associated with such disorder.

7) The presence or absence of working examples:

The examples in applicant's specification are drawn to the use of one macrolide compound, tacrolimus for the treatment of dry eye.

8) The quantity of experimentation necessary:

Since compound structure and activity for each pharmaceutical use must be determined from case to case by painstaking experimental study, one of ordinary skill in the art would be burdened with undue experimentation to determine all macrolide compounds which are capable of treating dry eye syndrome.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-14, 17 and 18 are rejected under 35 U.S.C. 102 (b) as being anticipated by WO 00/66122. The WO Patent teaches the use of the claim designated macrolide compound, FK506 in a pharmaceutical formulation for the treatment of dry eye. See the abstract. The above reference also teaches the use of polyvinyl alcohol in combination with FK506. See Example 1. The use of such compound for the treatment of dry eye would inherently treat the ocular discomfort associated with dry eye.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 7, 17 and 18 are rejected under 35 U.S.C. 102 (b) as being anticipated by Tsubota et al. Tsubota et al. Teach the use of cyclosporine A for the treatment of dry eye at the concentration of 0.05%. See page 124. the treatment of dry eye would inherently eliminate the discomfort associated with such disorder.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 15, 16 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/66122 and Peyman (U.S. Patent 6, 489,335).

WO patent teaches the use of the claim designated macrolide compound, FK506 in a pharmaceutical formulation for the treatment of dry eye. See the abstract. The use of polyvinyl alcohol is also taught by the above reference. See Example 1. Peyman teaches that the patient suffering from dry eye disease complain of mild to sever symptoms, with signs ranging from superficial keratitis to corneal perforation. See column 1, lines 16-19. It would have been obvious to a person skilled in the art to treat the ocular surface damage associated with dry eye by treating the dry eye, considering the secondary reference 's teachings that such damage and discomfort are part of dry eye.

One skilled in the art would have been motivated to combine the teachings of the above references, since one relates to the use of FK506 for the treatment of dry eye and the other relates to the ocular damage as a part of dry eye and indicative of a person having dry eye. To use a compound being used for the treatment of dry eye and use it to eliminate the damage associated with dry eye would have been obvious to a person skilled in the art in the absence of evidence to the contrary. Applicant has presented no evidence to establish the unexpected or unobvious nature of the claimed invention, and as such, claims 16 and 19 are properly rejected under 35 U.S.C. 103.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 10/354,083. Although the conflicting claims are not identical, they are not patentably distinct from each other because overlap. The claims of the co-pending application are drawn to a method of treating ocular disease and more specifically

treating dry eye using a macrolide compound, FK506 in a subject in need thereof. The claims of the instant application are drawn to the use of a macrolide compound in general and specifically FK-506 in a human patient for the treatment of dry eye. From the claims of the co-pending application it would have been obvious to use a macorlide compound for the treatment of dry eye in a human patient.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3, 4, 6 and 8-12 of copending Application No. 09/926,411. Although the conflicting claims are not identical, they are not patentably distinct from each other because they overlap. The claims of the co-pending application are drawn to a method of a macrolide compound and more specifically FK506 for the treatment of dry eye in a subject in need of such treatment. The claims of the instant application are drawn to the use of a macrolide compound specifically Fk506 for the treatment of dry eye in a human patient. It would

have been obvious to use a macrolide compound in a human patent from the teachings of the co-pending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh Fay whose telephone number is (571) 272-0573. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z.F

ZOHREH FAY
PRIMARY EXAMINER
GROUP 1200

zohreh Fay